

Appl. No. 10/017,223
Amdmt dated
Reply to Office Action of July 21, 2003

REMARKS

Claims 36-41 are pending in the present application. Claims 36, 38, and 41 are amended. No new matter was added by these amendments. Applicants respectfully request consideration of the present claims in view of the foregoing amendments and the following remarks.

Obviousness-Type Double Patenting Rejection

The Examiner rejected pending Claims 36-41, under the judicially created doctrine of obviousness-type double patenting, as unpatentable over the following U.S. patents:

- U.S. Patent No. 6,359,014 (hereinafter the '014 patent) – Claims 1, 2, 5, 6, 11 and 16;
- U.S. Patent No. 5,691,387 (hereinafter the '387 patent) – Claims 4, 7, 11 and 18;
- U.S. Patent No. RE 37,285 (hereinafter the '285 patent) – Claims 4, 7, 11 and 18;
- U.S. Patent No. 5,674,911 (hereinafter the '911 patent) – Claim 1.

In an effort to facilitate prosecution, Applicants provide herewith a terminal disclaimer for overcoming the rejection based on nonstatutory double patenting since the conflicting patents and present application are commonly owned. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection of Claims 36-41 under 35 U.S.C. §112, Second Paragraph

The Examiner rejected Claims 36-41 under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner asserted that the terms "substantially pure" and "non-pure" were unclear. Applicants respectfully traverse this rejection for the following reasons.

Applicants have amended the claims by adding that the "substantially pure polyoxypropylene/polyoxyethylene block copolymer composition is substantially free of unsaturated molecules". Support for substantially pure compositions having "less unsaturation"

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is found for example on page 26, lines 23-24 ("the low molecular weight molecules have unsaturated polymers present in the population."); page 27, lines 28-30 (copolymer with substantially no unsaturation); page 24, lines 1-7, and page 38, lines 8-11 (poloxamer preparations contain significant amounts of unsaturation, which is in part responsible for toxicity); page 25, lines 21-25 (need copolymer with less unsaturation"); page 26, lines 2-4, and page 26, lines 13-14 (copolymers are substantially free of unsaturation); and Examples VI-VIII show that commercially available poloxamer has unsaturation and the fraction containing the unsaturation can be removed.

Applicants maintain therefore, that the incorporation of this language, together with support and definitions provided in the specification along with the general level of skill in the art result in definite claims that distinctly define the invention. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Rejection of Claims 36, 38 and 40 under 35 U.S.C. §102(e)

The Examiner rejected Claims 36, 38 and 40 under 35 U.S.C. §102(e), as anticipated by U.S. Patent 5,674,911 to *Emanuele et al.* (the '911 patent). The Examiner asserted that the '911 patent teaches methods of treating infections by administering a POE/POP (polyoxyethylene/polyoxypropylene) block copolymer comprising a POE portion between 1,200 and 15,00[0] D, and wherein the POE portion represents 1-50% of the weight of the copolymer. The polydispersity of the copolymer may be 1.05. The Examiner also found that the copolymer in the '911 patent is less toxic than corresponding prior art compositions, and is substantially free of unsaturated molecules, and thus substantially pure. The Examiner concluded that the compound (copolymer) can be used to protect against damage to tissue cells by ameliorating infection. Applicants respectfully traverse this rejection for the following reasons.

According to MPEP 706.02(l)(1), a prior art rejection based on 35 U.S.C. §102(e) may be overcome if the prior art and the subject matter of the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person". In the present case, the current application is a continuation application with a

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chain of priority (through two continuation applications) extending to United States Patent Application Serial No. 07/847,874 (hereafter '874). The '874 patent was assigned to CytRx (copy of assignment is enclosed as Attachment A). Based on the language of the assignment and based on MPEP 306, in the case of a continuation application, a prior assignment recorded against the original application is applied to the continuation application because the assignment recorded against the original application gives the assignee rights to the subject matter common to both applications. Therefore, applicants respectfully submit that since both the cited reference and the present application are assigned to the same assignee, CytRx, the present rejection is rendered moot. Accordingly, Applicants respectfully request the withdrawal of this rejection.

Rejection of Claims 36, 38 and 40 under 35 U.S.C. §102(f)

The Examiner rejected Claims 36, 38 and 40 under 35 U.S.C. §102(f), as anticipated by the '911 patent. The Examiner found that the '911 patent lists two inventors not listed on the present application, and that the present application lists two inventors not listed on the '911 patent. The Examiner concluded, based on his prior 102(e) rejection, that it was not clear who invented the present application. Applicants respectfully traverse this rejection for the following reasons.

According to the MPEP 2137.01, inventorship is generally "to another" where there are different inventive entities with at least one inventor in common *except* where:

(A) the claimed invention in a later filed application is entitled to the benefit of an earlier filed application under 35 U.S.C. 120 (*an overlap of inventors rather than an identical inventive entity is permissible*)....The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art."; and

(B) the subject matter developed by another person and the claimed subject matter were, at the time the invention was made, owned by the same person or *subject to an obligation of assignment to the same person*. In this situation, a rejection under 35 U.S.C. 102(f)...is precluded by 35 U.S.C. 103. (emphasis added)

Based on the foregoing and Applicants' remarks set forth in response to the 35 U.S.C. 102(e) rejection above, applicants respectfully submit that the present rejection is rendered moot.

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Proof of common ownership is provided in the enclosed copy of the Assignment (Attachment A). Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

For at least the reasons given above, Applicants respectfully submit that Claims 36-41 define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

Applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited. The Examiner is invited and encouraged to contact the undersigned attorney of record at telephone number listed below, if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,

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